Message

From: Faeth, Lisa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=12AF792B39CC4B4FA8089976F3F8859F-LFAETH]
Sent: 11/24/2017 4:16:13 PM
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Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

U.S. Companies Split Over Global Chemical Classifications

Posted: Nov 24, 2017, 9:01 AM EST

By Sylvia Carignan

A United Nations proposal for a single, global classification list for chemicals used in trade is getting support—and some skeptical looks—from U.S. companies navigating the conflicting standards.

Companies in favor of a single, harmonized, global list of chemicals that would classify things like flammability and carcinogenicity, say it would reduce compliance costs and trade barriers by resolving conflicts between countries' chemical classifications. But, skeptics say there is an overwhelming amount of work to be done to create such a list.

Hach Co., which manufactures and distributes water quality testing technology, is in favor of the proposal.

"For a multi-national company like Hach, it is very difficult to keep up with national classification lists," James Lee, senior compliance analyst for chemicals at Hach Co., said.

In U.S. workplaces regulated by the Occupational Safety and Health Administration, hazard communication citations are among the most common violations, according to the agency. In fiscal 2015, hazard communication, which governs the evaluation of chemicals in the workplace, was the second most frequently cited standard.

The United Nations committee considering the chemical list proposal is scheduled to meet Dec. 6 through Dec. 8 in Geneva. But the committee needs to reach an agreement to take action on the list.

"There are concerns about how it should be developed, politics involved, how much work and time, and whether major players like [the European Union], China, and Japan will pay much attention to this list, or even oppose it," Lee said.

Lagging Behind

The "Globally Harmonized System of Classification and Labelling of Chemicals" is a framework a U.N. committee built to help countries classify the hazards of individual chemicals used in trade.

OSHA was involved with the system at its inception, and has been taking public input on the U.N. proposal for a global list based on the system's framework. The U.N. committee first started studying the possibility of a global list in 2008.

The classifications range from a chemical's carcinogenicity to flammability to environmental contamination risk. But, since countries have based their classifications on differing studies, or interpreted them differently, a single chemical's classification can vary from country to country.

One country may designate a chemical as a known carcinogen, while another may designate it as a suspected carcinogen.

Companies know that communicating chemical hazards is a clear priority, but the classifications are not well understood, Glenn Trout, president and chief executive officer of VelocityEHS, told Bloomberg Environment. "There's really a lot of confusion around how to label chemicals in the work environment," Trout said.

A global list proposed by the U.N. committee would align those classifications.

"Theoretically, it sounds like a great idea, but when you think about how it would be implemented, practically speaking, it is very complicated," Melissa McCaffrey, marketing communications director for VelocityEHS, told Bloomberg Environment.

A pilot program involving three chemicals, facilitated by the Organization for Economic Co-operation and Development, found that international bodies could reach a consensus on nonbinding classifications, but "substantial" effort was required. It would take potentially 18 to 20 months from selecting a chemical to finalizing its classifications, according to Edmund Baird, counsel for standards at the U.S. Department of Labor.

"It just seems like—not an insurmountable task, but there has to be a serious commitment," McCaffrey said.

OSHA has its own separate hazard communication rule, and doesn't plan to make changes to the rule as a result of global list feedback, according to an agency spokeswoman.

Weighing In

The American Petroleum Institute supports developing a list, as long as its classifications are not binding or mandatory. The institute's members include Alcoa Oil and Gas, Belle Fourche Pipeline, and Hess Corp.

A global list would help countries that don't have the resources to develop their own classifications, the institute said in a statement. But, the U.N. committee would need to determine how it chooses chemicals for the list and how it justifies each classification.

"These two key considerations become particularly salient when the available data are apparently conflicting," the institute said in a statement.

The U.N. committee has already agreed that the list be developed transparently and that the classifications be non-binding.

The American Cleaning Institute, which represents companies such as Cargill, Inc., Unilever, and Colgate-Palmolive, isn't supporting the list.

The list isn't a priority for the institute's members, and the effort necessary to build a list is a significant roadblock, Richard Sedlak, executive vice president for technical and international affairs at the American Cleaning Institute, said.

It's unclear whether the U.N. committee will set a timeline if it decides to build a list.

GREENWIRE ARTICLES

Buyout stories: 'We are kind of being hollowed out'

Three hundred seventy-two U.S. EPA employees took buyouts this year, with the enforcement and research offices among the hardest hit, according to agency data obtained by E&E News. "We are going to be able to hang a shingle on the outside of the building and still call it EPA," a union official said, "but we're not going to be able to still do what EPA used to do."

Federalist Society project hunts for burdensome rules

Maxine Joselow, E&E News reporter

Published: Wednesday, November 22, 2017

The Federalist Society has launched a project to identify regulations whose costs exceed the benefits.

The Regulatory Transparency Project, which kicked off this month, seeks to find rules and guidance that place an undue burden on the American economy.

Despite the best of intentions, government regulations can cause harm," said Devon Westhill, director of the project. "What we're trying to do is examine rules and guidance and the regulatory process itself to find areas where regulation seems to be doing more harm than good."

It's a frequent conservative talking point that red tape should be cut and the sprawling regulatory state should be trimmed. But Westhill said the project is nonpartisan, noting that the Federalist Society doesn't take a stance on specific law or policy initiatives.

The project comes as President Trump has made deregulation a top priority for his administration. Trump signed a January executive order requiring that two rules be revoked for every new one issued, followed by a February executive order requiring that agencies set up regulatory reform task forces.

But Westhill said the Regulatory Transparency Project has been in the works since spring 2016.

"While we're just announcing this, this is something that's been in the hopper since before the election of President Trump," Westhill said. "There's no idea that there would be a sympathetic ear at the federal level."

The project will consist of 12 working groups that each focus on an area of rulemaking, including antitrust and consumer protection, energy and environment, intellectual property, and labor and employment.

The energy and environment working group has eight members. All have academic credentials, and some have conservative pedigrees, with two previously serving in the George W. Bush administration and one having served in the Reagan administration.

Jeff Holmstead, chairman of the energy and environment working group and former assistant administrator of U.S. EPA's Office of Air and Radiation under President George W. Bush, said he hopes to foster meaningful conversations about regulatory reform.

"When this opportunity came along, I really viewed it as a way to help create the intellectual framework for regulatory reform," Holmstead said. "Regulations are basically a bad deal for society if the costs outweigh the benefits. And even when the benefits outweigh the costs of a particular regulation, that doesn't make it a good thing if there are less costly ways to achieve the same result."

So far, the group has produced two papers. The first criticized EPA's "expansive regulatory approach" to the Waters of the U.S. rule and called for "restoring meaningful limits" to the statute. The second called for repealing the Jones Act to unfetter American oil and gas production.

Richard Belzer, a member of the energy and environment working group and former staff economist in the Office of Management and Budget under President Reagan, said he hopes the group turns its attention next to the Safe Drinking Water Act.

"The last time it was reauthorized was 1996," he said. "What's going on, I think, is that the 1996 amendments to the law finally told EPA that they had to do benefit-cost analysis. And I think what they're discovering is that the costs outweigh the benefits."

CHEMICAL WATCH ARTICLES

Swiss chemical giant, Lonza, rolls out global preservatives strategy

Aims to defend ingredients for personal care and household products

22 November 2017 / Active substances, Biocides, Cleaning products, Global, Personal care

Swiss multinational Lonza has rolled out a global strategy, dedicated to ensuring a broad palette of preservatives remains available to the household and personal care products industries in the years ahead.

The chemical giant's consumer care division is investing in short-, medium- and long-term preservation programmes. The move comes partly in response to increasing regulatory scrutiny of traditional preservatives, which has thrown the cosmetics industry in particular into a crisis.

An ongoing goal is to defend existing ingredients, which are "supported by robust data packages and underpinned by regulatory compliance", Lonza says.

The company is working with relevant trade bodies and regulators to argue for keeping these on the market. Often this means addressing negative media attention, says Lonza's head of global marketing for preservation, Phil Hindley.

"It is inevitable that some companies in the market will be more sensitive towards such controversy than others, with a continuing dilemma being the battle between negative PR and actual regulatory restrictions," he says.

"We recognise there is a move away from certain 'controversial' chemistries, but equally that many formulators and personal care companies are continuing to use these, given their familiarity and longstanding adoption."

Bans and restrictions on widely used substances have come into force over the last two years in Europe and in the US, including for several parabens and the mixture of methylchloroisothiazolinone and methylisothiazolinone (MCI/MI). Other compounds are facing scrutiny from authorities and NGOs.

Innovation

Meanwhile, Lonza is future-proofing its portfolio by formulating new preservative systems, based on options including organic acids and multifunctional additives.

A growing trend in the personal and home care sectors - blending recognised actives with inert ingredients or other co-formulants - can improve a preservative system's efficacy and reduce the content of single ingredients in the final formulation. This can help in complying with restrictions, or reducing the potential for allergies.

Multifunctional additives are not regulated as preservatives, but can contribute towards the effectiveness of the final product. They can be used as either standalone systems that offer a preservation effect in addition to other benefits, or as potentiators that boost the activity of existing active substances.

Although multifunctionals can add a level of complexity to a product, they have a "solid place" in the preservation market, says Mr Hindley. Nevertheless, they are also beginning to give concern to authorities and NGOs. Sweden's EPA has flagged up that with a lack of research on their use, these additives could come with unknown human health risks.

Organic acids, meanwhile, are growing in popularity and adoption, particularly in personal care markets, he says.

Lonza's long-term goal is to develop two new preservative active substances for a number of applications. A "significant investment" for the company, it is expecting to progress these within the next few years.

Joint efforts

Mr Hindley adds that Lonza's strategy fits into a joint effort by industry to defend preservatives. "There are trade bodies working to [do this] on behalf of their members; some of our competitors are making efforts too. And outside of that we are also communicating with the regulators about this issue."

The European Commission acknowledged earlier this year that reducing the palette of preservatives available to formulators "creates real public health problems" because it means that consumers are exposed to higher levels of those remaining.

And Cosmetics Europe has been vocal in its defence of preservatives, calling the shrinking pool of substances available "a crisis".

Meanwhile, US business group the Green Chemistry and Commerce Council (GC3) has run a competition with the aim of identifying promising safe preservation systems for personal care and household products, and help bring them to market. It closed in the summer with 48 submissions for potential new systems.

Judges from 11 companies, including Lonza, are currently evaluating them.

Related Articles

- The big preservatives 'crisis'
- EU bans five parabens, restricts triclosan in cosmetics
- European Commission restricts three cosmetics preservatives
- Swedish government considers action on preservatives in cosmetics
- Industry must avoid stigmatising preservatives, says EU Commission
- The big preservatives 'crisis'
- US business group evaluating 48 potential new preservation systems

Further Information:

- Lonza preservatives web page

Niceatm invites scientists to build oral toxicity models

22 November 2017 / Alternative approaches to testing, United States

The US National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (Niceatm) has invited researchers to take part in a global project to develop *in silico* models to predict acute oral systemic toxicity, using available rodent data.

Acute oral toxicity is one of the US EPA "six-pack" tests, which result in high animal use worldwide. Tests are for acute oral, dermal and inhalation systemic toxicity, as well as eye and skin irritation and skin sensitisation.

The Interagency Coordinating Committee on the Validation of Alternative Methods (Iccvam) is organising the international modelling project through its acute toxicity workgroup. One of Iccvam's "high-priority efforts" is to develop alternative test methods for the six-pack.

Niceatm and the EPA National Center for Computational Toxicology have collected a large body of rat acute oral lethality data. Researchers interested in joining the project should build and test models, using this. A 'training' data set is already available on the Niceatm website and prediction data will be released in December.

Models that meet certain criteria will be used to generate consensus predictions for acute oral toxicity endpoints of particular interest to regulatory agencies, according to Niceatm.

Toxicity predictions generated by the models will also be made publicly available on the EPA's chemistry dashboard.

Prediction results should be submitted by 9 February 2018. The results will be presented at a workshop in April.

Further Information:

- Niceatm call

Thailand's draft chemical inventory expected by year end

Limited searches possible, based on Cas numbers

22 November 2017 / Safety data sheets, Substance notification & inventories, Thailand

The first draft of Thailand's existing chemical inventory is expected before the end of the year, delegates at Chemical Watch's Regulatory Summit Asia have heard.

Dr Piyatida Pukclai, regulatory policy director at consultancy Dr Knoell Thailand, said that it will include data collected up until December 2016. However, she noted, there is currently no date for the official first full version.

Dr Pukclai also covered recent announcements on confidential business information (CBI) by the Department of Industrial Works (DIW). These include a minimum period for CBI requests of eight-12 months and the rules for rejecting a CBI submission, which are currently published in Thai.

She also discussed changes to Thailand's Hazardous Substance Act. The updated law is "expected soon" and will include 22 new substances.

Dr Pukclai told delegates that from October, the ministry has allowed a Thai subsidiary company of a manufacturer – or an authorised agent – to consult with them on behalf of importers.

She also reported on a new online tool, called the hazardous substance single submission (HSSS), that can be used for the registration of type two and three hazardous substances and for the licensing of type three substances.

Sunny Lee in Singapore

More on this on CW+AsiaHub

Related Articles

- Thailand's draft chemical inventory expected by year end

Further Information:

- Hazardous substance single submission (HSSS) online

Vietnam sets limits on formaldehyde and azo colourants in textiles

23 November 2017 / Textiles & apparel, Vietnam

Vietnam's Ministry of Industry and Trade has published limits on the amount of formaldehyde and azo colourants in textiles. The new regulation takes effect on 1 May 2018.

Under the new rules, the limits of formaldehyde are:

- 30mg/kg in textile products for children under three;
- 75mg/kg in textile products in direct contact with the skin; and
- 300mg/kg in textile products with no direct skin contact.

It also specifies the limit of 30mg/kg for 22 aromatic amines converted from azo colourants.

The ministry published a draft on the limits earlier this year. The new rules will be introduced under Circular No 21/2017/TT-BCT: "the national technical regulation on the content of formaldehyde and certain aromatic amines derived from azo colourants in textile products."

More on this on *CW+AsiaHub*

Related Articles

- Vietnam to limit formaldehyde and azo colourants in textiles
- Vietnam sets limits on formaldehyde and azo colourants in textiles

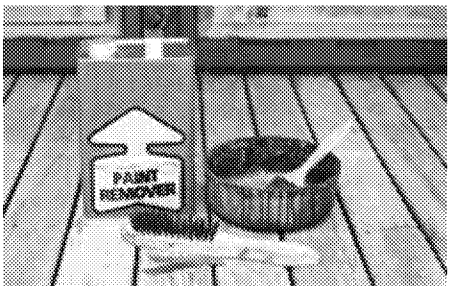
Further Information:

- MIT announcement (in Vietnamese)

California moves on methylene chloride paint strippers under SCP programme

'Priority product' designation will require 'alternatives analysis'

23 November 2017 / Alternatives assessment & substitution, Built environment, TSCA, United States



California's Department of Toxic Substances Control (DTSC) has proposed regulations to name paint strippers containing methylene chloride a "priority product". The move comes under the state's Safer Consumer Products (SCP) programme and is the next step in a process that could lead to the products being restricted or banned in California.

The agency said it will accept written comments until 18 January, and will hold a public hearing on 8 January.

Once the regulation is finalised, manufacturers of such products sold in the state will have 60 days to register with the department and begin an analysis to determine if a safer alternative is possible.

The DTSC named the first three chemicals to be scrutinised under the programme in 2014. And children's sleeping items containing the flame retardants TDCPP or TCEP officially became the first "priority product" on 1 July. Alternatives analyses for this should be underway. The public comment period on the second priority product – spray polyurethane foam (SPF) containing MDI – ended on 6 June.

It took more than eight months to move from consultation to finalised regulations on the flame retardants, so it is likely alternatives analyses for methylene chloride paint strippers will not begin until the end of 2018.

Methylene chloride paint strippers are not only carcinogenic and neurotoxic, the DTSC says, but "high-level acute exposures can be fatal and there are numerous worker and consumer deaths" associated with their use.

The requirements will apply to any methylene chloride product sold in California "as a chemical substance designed to break down paint, varnish, or any other surface coating to facilitate its removal from any surface."

Separate California regulations already ban the use of methylene chloride in a variety of consumer cleaning products.

Listing as a priority product "sets in motion a strategy to reduce human exposure," the DTSC said in its current proposal, but it is unknown what regulatory action might be taken in response to alternatives analyses.

"Because each manufacturer's proposal will address its specific business situation, DTSC cannot predetermine the actions that paint or varnish manufacturers would need to take, either individually or collectively, to meet the goals of protecting people and the environment and advance green chemistry or green engineering principles," the agency said.

EPA considering federal ban

In the last days of the Obama administration, the US EPA issued a proposed rule to ban all consumer, and most commercial, use of methylene chloride as a paint stripper. And the agency solicited feedback on whether to additionally ban n-methylpyrrolidone (NMP), or impose rules on concentration, workplace protections and labelling.

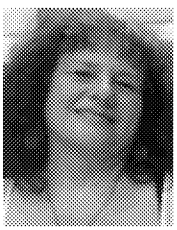
The January proposal specifically excluded furniture refinishing, indicating that the EPA would "propose such a regulation at a later date."

At a September EPA stakeholder workshop, manufacturers and industrial users argued for requiring protective measures and possibly restricting the use of methylene chloride to commercial products, arguing that an outright ban would make furniture stripping unprofitable.

The workshop could be a clue that the Trump administration might follow through on some methylene chloride regulation. In addition, the semiannual regulatory agenda the EPA published on 24 August indicated that the agency plans to publish a supplemental notice of proposed rulemaking, amending its original proposal.

There is no requirement that the EPA act on that rule. However, methylene chloride is also being reviewed separately as one of the first ten priority substances subject to mandatory risk evaluation under the new TSCA. Furniture refinishing is included in the scope of that evaluation.

Sale of paint strippers containing methylene chloride is restricted in the EU under REACH.



Julie A Miller

North American Desk Editor

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- Science advisers question California AA guidance lack of specificity
- California names first priority products for alternatives assessment
- California designates first priority product under SCP programme
- Industry speaks out against California spray polyurethane foam proposal
- US EPA proposes prohibitions on methylene chloride, NMP
- Industry urges US EPA against full paint stripper ban
- EPA may progress proposed methylene chloride and NMP restrictions
- EPA names first ten chemicals for new TSCA evaluations

Further Information:

- DTSC documents on methylene

EU enforcement pilot to target phthalates, flame retardants

Substances in articles project to include electrical products, building materials

23 November 2017 / Built environment, Electrical & electronics, Enforcement, Europe, Halocarbons, Phthalates, REACH

Echa's Enforcement Forum has started work on a pilot project to verify compliance with the notification and communication obligations of substances in articles in REACH. It will specifically target seven substances, or groups of substances, including flame retardants and phthalates.

National enforcement actions, reports from authorities and NGOs, and the low number of notifications being made to Echa indicate that industry is failing to meet its obligations.

The pilot was first announced in November 2015, two months after the European Court of Justice (ECJ) ruling that the 0.1% threshold for notifying SVHCs in articles applies to each component of a complex product rather than the entire product.

The project aims to:

- check compliance of producers, importers and suppliers of articles with their obligations (REACH Articles 7 and 33);
- raise awareness and understanding of legal obligations and the level of compliance among duty holders;
- build a better picture of the actual level of compliance by suppliers of articles;
- identify reasons for non-compliance and decide whether Echa, the Commission and/or member states competent authorities need to do more, such as providing support to duty holders; and
- gather experience and establish enforcement methods for a potential future large-scale check of these obligations.

Echa says electrical products, building materials and interior articles are examples of consumer goods that may be inspected. The substances, or groups of, that it will focus on are:

- brominated flame retardants;
- phosphorous flame retardants;
- short-chain chloroparaffins;
- phthalates;

- aprotic polar solvents;
- perfluorinated substances; and
- phenolic benzotriazoles.

The project runs from from October 2017 to June 2018. A report of the results is expected by the end of next November.

At the end of June, Echa published the long awaited revision of its guidance on substances in articles. The agency said the "comprehensive update", which was expected in 2016, gives more clarity on communication and notification obligations when articles contain SVHCs. It includes new examples, which it says are in line with the judgement of the ECJ ruling.

Forum meeting

Textile articles will also be addressed in the pilot, Forum chair Katja vom Hofe told Chemical Watch. This subject was raised at the November Forum meeting by Mauro Scalia, manager of sustainable business at European textiles industry association Euratex. He said the association has faced challenges with some non-compliant companies and asked if there was any enforcement activity around textiles.

"We said we have a number of enforcement projects, which – among other types of articles – are looking into textiles," Ms vom Hofe said. This includes the recently concluded fourth REACH-En-Force (Ref-4) project, which had "quite a high number" of checks for textiles.

Cefic REACH director Erwin Annys also spoke at the meeting about the enforcement of imported substances and how to protect competition for European manufacturers, which face strict controls inside the EU. Robust checks of imported substances are needed because, he said, Cefic believes some non-EU manufacturers are potentially not following the rules of REACH.

The Forum has "a very high percentage" of checks that address imports, Ms vom Hofe said, and added that "at least half" of the substances or products that it inspects are imported because it knows there is "a fairly high chance" they might not be compliant.

The third authorisation pilot project to be carried out by EU national enforcement authorities (NEAs) in 2019 will cover chromates with sunset dates that have passed.

In June, the Forum announced that NEA inspectors will focus on registration obligations – including substances registered as intermediates – under Ref-7. It also launched its first joint action agreement with its accredited stakeholder organisations (ASOs) – trade bodies and NGOs – to improve the quality of safety data sheets.

The working group is now set up and there is "lots of willingness" among its members, who will report at the end of next year on their findings, Ms vom Hofe says.

The next Forum meeting will take place in March 2018.

Luke Buxton

Europe desk editor

Related Articles

- National authorities 'committed to coordinating enforcement' of substances in articles
- European Court of Justice rules on SVHCs in articles
- Echa issues updated guidance on substances in articles
- REACH enforcement project finds phthalates in toys a 'big problem'
- Third EU authorisation enforcement project to cover chromates
- EU enforcement project to check REACH registrations in 2019

Further Information:

- Echa press release
- Enforcement Forum

EPA lists chemicals reported under TSCA inventory notification rule

23 November 2017 / Substance notification & inventories, TSCA, United States

The US EPA has published an updated list of more than 10,000 chemical substances that have been reported under the TSCA inventory notification rule.

The rule requires manufacturers and importers to report by 7 February 2018 all nonexempt substances that they used in the ten-year 'lookback period' ending 21 June 2016.

Processors (downstream users) have until 5 October 2018. They are not required to report but must do so to avoid having a chemical labelled "inactive".

Agency officials said last month that a final inventory would be published within two months of the October deadline.

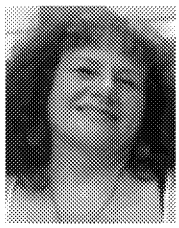
The list will be the starting point for identifying high and low priority substances for assessment under TSCA.

The list of 10,370 chemicals published on 22 November includes reports received by 10 November, and the agency plans to update it regularly.

"This list is for informational purposes only" and the listed substances "are not exempt from retrospective reporting by other manufacturers" unless they have obtained a Central Data Exchange (CDX) receipt from the manufacturer who has reported it, the EPA's notice says.

It will probably be most useful to processors, who are not required to report but may want to ensure that chemicals they deal with are on the active inventory.

The EPA has developed a separate list of 13,209 active chemical substances that are exempt from reporting. They are substances reported under the 2012 and 2016 Chemical Data Reporting (CDR) rule, and in Notices of Commencement received during the ten-year lookback period.



Julie A Miller

North American Desk Editor

Related Articles

- Final TSCA inventory notification rule eases reporting burden
- Downstream users express concern at TSCA inventory requirements

Further Information:

- Substances reported through 10 November
- Substances exempt from reporting

Canada will not regulate 2-MBS

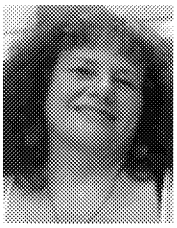
23 November 2017 / Canada, Environmental Protection Act, Personal care

The Canadian government has decided that 2-MBS (benzenesulfonamide, 2-methyl) does not pose health or environmental risks, sufficient to warrant regulation under the country's environmental protection act (Cepa).

The substance is used primarily as an intermediate for fluorescent pigments and plasticiser resins, and as a plasticiser for hot-melt adhesives. It is also used as an ingredient in nail polish, and may be formed in small amounts during the manufacture of the food additive saccharin.

The risk assessment of these substances, and the proposal to take no action on them, was published for public consultation in February.

The final determination was published in the 18 November *Gazette*.



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Related Articles

- Canada publishes draft screening assessment for 2-MBS

Further Information:

- Canada Gazette

US Senate spending bill would eliminate IRIS programme

Appropriations measure would restore more than half of Trump's proposed cuts

23 November 2017 / TSCA, United States

The Senate Appropriations Committee has released a proposal that would eliminate the US EPA's Integrated Risk Information System (IRIS) programme. Such a move would potentially give control of chemical research directly to political appointees who run the agency's regulatory agenda.

The Senate committee's version of the fiscal 2018 appropriations bill covering the EPA was published on its website on 20 November. It would cut the agency's overall funding by $149m. But it provides $3.8bn more than the counterpart legislation approved by the House in September and $22.5bn above the 30% cut called for in the Trump administration's requested budget.

The Senate bill includes $111.6m for the "chemical safety and sustainability" line item that funds chemical research. This would be a $15.3m cut, but is more generous than the House and restores more than half of the $27m cut proposed by the administration.

Eliminating IRIS

However, the report accompanying the bill's text says the committee has not provided funding for IRIS. "In order to ensure that important chemical assessment work is completed, the Committee has transferred resources within the agency from IRIS to help implement the Lautenberg Chemical Safety Act," it said.

Chemical safety and sustainability is one of six thematic research programmes managed by the Office of Research and Development (ORD). Actual research is carried out by seven laboratory organisations. IRIS is part of one such laboratory, the National Center for Environmental Assessment (NCEA), which has facilities in Ohio and North Carolina.

"The bill imposes the IRIS workload onto the recently-reformed Toxic Substances Control Act (TSCA) programme, which was not designed to accommodate the breadth of the IRIS programme's responsibilities," minority Democrats on the Senate Appropriations Committee said in a statement.

It is not clear exactly how the committee's majority envisions redistributing funding and responsibilities, but the office in charge of "implementing" the Lautenberg Act's TSCA reforms is the Office of Chemical Safety and Pollution Prevention (OCSPP). That is the regulatory division that would be headed by Michael Dourson if his nomination is not defeated in the Senate.

"At best a small fraction of its responsibilities — and only one-third of its funding — would be re-allocated" to the OCSPP, Jennifer McPartland, a senior scientist at the Environmental Defense Fund (EDF), wrote in criticising the Senate bill's treatment of IRIS.

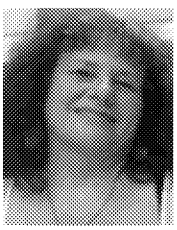
Moving IRIS staff from the non-regulatory ORD into the OCSPP would cost the EPA "scientific expertise that serves the entire agency, severely undermining the legal responsibilities Congress has given it," and would "sever the independence between scientific review and regulatory decisions informed by such reviews," Dr McPartland wrote.

She noted that the EPA's website says placing the IRIS programme within ORD "ensures that IRIS can develop impartial toxicity information independent of its use by EPA's program and regional offices."

Alternative test methods

The Senate panel's report also included unusually specific language regarding development of a strategic plan to promote alternative test methods that is required under TSCA. EPA officials discussed the emerging plan at a recent public meeting. The process of developing the plan should involve public meetings, consultation with "the scientific community and the public" and a final version "documenting response to, and disposition of, public comments". The committee asked for a progress report by 30 September 2018.

Finally, the report addresses a TSCA provision allowing the EPA to collect fees from manufacturers. The bill would earmark $10m in federal funds that would be replaced by the fees that are anticipated to come in during fiscal 2018.



Julie A Miller

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- House approves 2018 spending bills, rejects further US EPA cuts
- Trump budget proposal would cut EPA funding by a third
- Opposition by Republican senators casts doubt on Dourson nomination
- US EPA has first public input on alternative test methods for TSCA

Further Information:

- Senate appropriations report
- Democrat news release

Russia sends implementation plan to Stockholm Convention

23 November 2017 / Persistent organic pollutants, Russia

The Russian Federation has submitted its national plan on implementing the Stockholm Convention on persistent organic pollutants (POPs).

Each party to the convention is required to develop such a plan, which the Secretariat then presents to the next Conference of the Parties.

The national implementation plan (NIP) was approved by the country's Ministry of Natural Resources on 3 October.

The NIP consists of two sections. The first deals with activities to be implemented by 2020, and includes seven objectives:

- improved legal regulation of POPs;
- an improved management system for POPs;
- the destruction/disposal of accumulated pesticides, industrial wastes and equipment containing POPs;
- cleaning of contaminated territories;
- monitoring of the pollutants in the environment and population health in relation to their effects;
- improved information and education; and
- exchange of information with the Secretariat and Parties to the Stockholm Convention.

The second section deals with long-term versions of these activities for the years 2021-2028.

Further Information:

- NIPs

US children's products trade group refutes NGO chemical ranking

Mind the Store defends retailer report card

23 November 2017 / United States

US trade group the Juvenile Products Manufacturers Association criticised an NGO report — which grades retailers' on their efforts to tackle chemicals of concern — for implying children's products could be toxic.

Kelly Mariotti, executive director of the JPMA, told Chemical Watch that children's products "cannot present either acute or chronic hazards to children" because they are "heavily regulated" under the Federal Hazardous Substance Act and Consumer Product Safety Act, and most products were tested by government-accredited laboratories before sale.

She said: "We are extremely confident these products are safe and would be verified as safe by any board-certified toxicologist. The claims here are false and misleading, which is why we urge all responsible parties to either verify them or retract them from publication."

The 'report card' by the Mind the Store coalition of NGOs ranked 30 retailers across 11 sectors on their chemicals policies.

The eight baby and children's products retailers assessed received an average D+ grade, matching the average retailer performance on safer chemicals.

Co-author of the report and executive director of the Environmental Health Strategy Center, Mike Belliveau, told Chemical Watch: "We did find that the baby product sector is a laggard in ensuring the chemical safety of the products they sell. That should be a wake-up call to action for most consumers and the retailers."

In a Mind the Store press release, Bobbi Wilding, coordinator of the Getting Ready for Baby campaign, called on Toys R Us subsidiary Babies R Us, and Buybuy Baby to make "vast improvements" in 2018.

However, Frederick Locker, attorney at Locker Greenberg & Brainin LLP, the independent general counsel for JPMA, told Chemical Watch: "The premise of the reports and supporting campaigns is a claim the mere presence of a substance or material renders products toxic; rather than a toxicological assessment of hazardous exposure. There is a significant distinction."

'Drop in the bucket'

In response to the JPMA's comments, Mr Belliveau said: "This report is not an assessment of the safety of an individual product, it is a comparison of leaders and laggards in the retail sector regarding policies and practices that are designed to ensure that chemical safety in the products they buy and sell."

He added: "There are thousands of dangerous chemicals and untested chemicals in commerce. The US government has only outright banned two classes of chemicals in toys in recent times, which is lead compounds and phthalates. That's a drop in the bucket."

Ms Wilding said in response to the JPMA: "Baby products retailers were evaluated with the same criteria looking at their corporate practices. You don't need to look any further than the Washington State database on chemicals of concerns in children's products to realise that there are chemicals of concern being reported by manufacturers in products made for children."

She added: "We stand by our concern in making sure that products made for children are made without chemicals of concern, because we are concerned about eliminating the hazards."

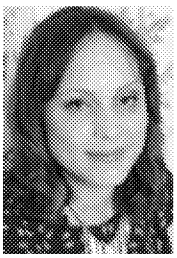
Toys R Us

Toys R Us and its subsidiary Babies R Us, received an F grade, scoring five out of a possible 135 points and ranking 22nd out of 30 retailers.

The report says the store is "failing to publicly address toxic chemicals in the products they sell". Toys R Us missed out on points because it does not publish a corporate responsibility report or other public facing documents that summarise their efforts to address chemicals of concern.

A spokesperson for Toys R Us said that, because the report based its grades on publicly available information, it did not reflect its actual policies or programmes.

Buybuy Baby did not respond to Chemical Watch's request for comment by the time of publishing.



Tammy Lovell

Business Reporter

Related Articles

- Apple comes top in US retailer chemical ranking

Further Information:

- Retailer report card
- Getting Ready for Baby campaign

Head of UN Environment calls for 'targeted intervention' on hazardous chemicals

Executive director sets out framework ahead of global environment meeting

23 November 2017 / Global

In his vision to combat the rise in global pollution, UN Environment executive director, Erik Solheim (pictured), has set out measures to address hazardous chemicals.

Mr Solheim's report, *Towards a Pollution-Free Planet*, outlines actions to tackle the issue around the world and highlights chemicals of concern as a "hard-hitting" target. The report has been prepared for the third United Nations Environment Assembly (Unea-3) in Nairobi, Kenya between 4 and 6 December which has the overarching theme of pollution.

The framework targets substances already addressed through multilateral agreements — such as those covered by the UN's Basel, Rotterdam, Stockholm and Minamata Conventions. The aim will be to identify — and take action on — areas where implementation and enforcement of these substances needs to be strengthened and scaled up. Examples of where action can be taken include:

- identifying alternatives;
- providing additional finances to curb risks;
- capacity building; and
- encouraging industry support.

A second target category will be pollutants where scientific evidence already exists to justify new interventions to reduce the risk that they pose, for example for heavy metals. Actions, it says, could include enforcing new emissions standards and improving chemical labelling schemes.

A third category focuses on substances where the emerging scientific evidence of the "nature and magnitude of their risk to human health and the environment points to the need for further investigation and better understanding of those risks", such as endocrine-disrupting chemicals.

"There is a need to step up research into, and build understanding of, the potential risks of these substances, especially in developing countries," the report says.

Chemicals and waste

The report sets out 50 broad policy options to address air, water, land/soil, marine and coastal, and chemicals and waste pollution. Of these, 19 come under chemicals and waste.

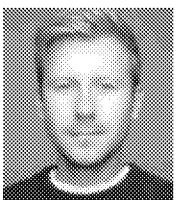
These include:

- adopt sound chemicals management and advance sustainable chemistry within business approaches, policies and practices;

- increase efforts to deploy locally safe, effective, affordable and environmentally sound alternatives to chemicals of concern, including DDT (dichlorodiphenyltrichloroethane), PCBs (polychlorinated biphenyls), asbestos, lead and mercury;
- accelerate the implementation of the Basel, Rotterdam and Stockholm conventions, the Minamata Convention and the Strategic Approach to International Chemicals Management in a coordinated manner at the national level;
- improve knowledge relating to chemicals in products throughout their life cycle (production, use, consumption and disposal); and
- increase publicly available information and monitor data on the presence of chemicals in the environment, in humans and in pollution hotspots.

Last month, the EU Council of Ministers called on UN member states to help increase knowledge of hazardous substances, encourage the exchange of information on chemicals in products and replace hazardous chemicals with safer alternatives.

It called upon the assembly meeting to decide upon concrete measures to deal with specific issues such as endocrine disruptors and heavy metals.



Leigh Stringer

Global Business Editor

Related Articles

- EU Council calls on Unea to increase hazardous chemicals knowledge

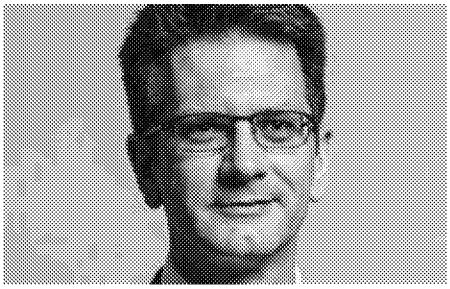
Further Information:

- UN report

UK government wants Brexit deal validity for REACH registrations

Chemicals regulations 'key topic in opening phase of negotiations', minister says

23 November 2017 / REACH, Substance registration, United Kingdom



The UK government has reaffirmed its position that it wants existing REACH registrations and authorisations to remain valid in both the EU and UK markets after Brexit.

And, according to a government spokeperson, the matter has been a key topic of the opening phase of Brexit negotiations.

The comments were due to be made in a speech by Steve Baker, a junior minister in the Department for Exiting the European Union at last week's Brexit conference, which was hosted by the Chemical Industries Association (CIA). Mr Baker was forced to pull out at the last minute but supplied his speaker's notes to the organisation.

"The UK's position is clear," the notes say. "We want existing registrations, authorisations and approvals to remain valid in both the EU and UK markets. Clearly, this is in the interests of businesses in the UK and the EU. [The government] recognises the complex compliance activity that takes place through supply chains.

"We understand the concerns of businesses regarding the validity of their REACH registrations, as well as the costs that industry have already invested to comply with REACH," he says. "We have been listening to what businesses and others have been telling us about their concerns for the future and the potential impacts and opportunities of EU Exit. We will continue do this.

"I can assure you that this matter has been a key topic of the opening phase of negotiations. Our position paper on this in August sets out the UK's principles for ensuring goods continue to be available on UK and EU markets."

The CBA, CIA and Cefic have all called for regulatory consistency and for the country to remain in REACH. Failure to do so, they say, might result in British registrations and authorisation applications becoming invalid.

Continuity

In the short-term, Mr Baker's notes say, the EU Withdrawal Bill will provide "continuity" for the chemicals sector, because it is "designed to ensure" that the UK exits the Union with "certainty, continuity and control".

According to the notes, the UK wants:

- high standards of protection of human health and the environment;
- to make sure it can respond to emerging risks; and
- to make sure it can minimise barriers to trade.

Britain and the EU start from "the unique position" of regulatory alignment, Mr Baker says. "So the question for us now, in building a new economic partnership, is not how we bring our rules and regulations closer together, but how we manage our interdependence in a way that maintains the balance of rights and obligations that flow from this regulatory relationship."

It is in the "mutual interests" of the UK and EU chemicals industries to agree a deal that allows the greatest possible tariff-free and barrier-free trade in chemicals.

In the "unlikely scenario" that no mutually satisfactory agreement can be reached, the government will "make sure we continue to have a functioning chemicals regulatory and enforcement system".

Earlier this month, CIA and Cefic said failure to secure a transition period and a new UK/EU trade agreement after Brexit could cost the chemicals industry an extra €1.5bn a year.

Collaboration

The chemicals sector, Mr Baker's notes say, is "the industry of industries", and one of the UK's "core objectives" is to continue to collaborate with European partners on major science, research and technology initiatives.

"The UK will look to build on its unique relationship with the EU and establish an agreement on science and innovation that ensures the valuable research links between us continue to grow."

And the notes say "stakeholder engagement is a central element" of the government's plan to build its negotiating positions.

Industry and NGOs have both called for business to "speak up" for a better Brexit, through cooperation and more visibly communicating their concerns.

Luke Buxton

Europe desk editor

Related Articles

- UK minister wants REACH 'mutual recognition' accord
- Chemicals industry 'must work together' to limit Brexit damage
- Cefic, CIA spell out 'hard' Brexit costs to chemicals industry
- Cefic, CIA spell out 'hard' Brexit costs to chemicals industry

- Businesses 'need to speak up' for a better Brexit

Further Information:

- Steve Baker speaker's notes

Echa round-up

23 November 2017 / Classification, labelling and packaging Regulation, Europe, SVHCs

Extension of public consultation on CLH

Echa will extend the public consultation comment period on harmonised classification and labelling (CLH) proposals from 45 to 60 days from 1 January 2018. The reason for this is to allow more time for the parties concerned to prepare and submit their comments, the agency says.

Testing proposals

The agency has received twelve testing proposals for eight substances. The deadline for submitting information is 8 January 2018.

Translations:

- **Guidance on labelling and packaging**

Translations of the updated Guidance on labelling and packaging (version 3.0) published in July, are now available in 23 EU languages on Echa's website.

- **Information on manual verification**

The agency's advice for manual verification at the completeness check was updated in October. Translations in 22 EU languages are now available.

Survey of SVHC Roadmap tools

Echa is reviewing, with member states and the European Commission, implementation of the roadmap for SVHC identification and REACH risk management measures from now to 2020 (the SVHC Roadmap).

In particular, the agency is looking for ideas on how to improve current tools that have been developed to enhance and support the transparency and predictability of the work of authorities.

Survey of poison centres website

Echa is planning an update of the poison centres website and would like users' opinion on the current content. Its online survey will take about five to ten minutes to complete, it says.

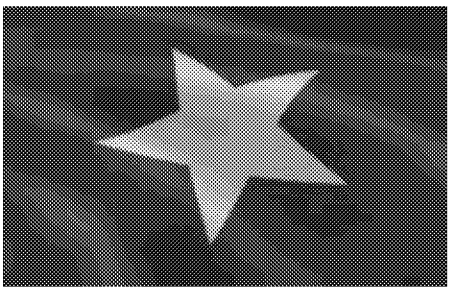
Further Information:

- Current testing proposals
- Guidance on labelling and packaging

- Manuals
- Online survey: SVHC Roadmap and tools
- Online survey: poison centres website

Vietnam to introduce national database by 2019 at earliest

23 November 2017 / Vietnam



Vietnam aims to complete its first comprehensive national chemical inventory and database by 2019, an official at its chemicals agency Vinachemia said.

Speaking at the International Chemical Management Conference earlier this month, Nguyen Thi Ha, head of the organisation's Conventions and International Cooperation Division, said that one of its priorities is the development of a national chemical database and inventory.

The government is funding the project with support from Japan's Ministry of Economy, Trade and Industry (Meti). The agency published a draft inventory in March 2017.

The new database and inventory aim to reach an effective list of between 300 and 400 chemical substances.

"We expect that we can complete this task at the earliest by 2019," she said.

Details of Decree 113/2017/ND-CP unveiled

During the conference, Ms Ha also introduced the key points of Decree 113/2017/ND-CP which regulates the declaration of manufacturing/import of chemicals. The rules take effect on 25 November and include:

- adding requirement for the bottling and packaging of chemicals;
- adding clear criteria for each list of chemicals based on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) classification;
- removing the current list of toxic chemicals;
- removing the requirement for the registration for the use of chemicals; and
- mandating that reporting requirements to be integrated in general reports on all chemical activities.

The aim is to ease numerous onerous or unnecessary restrictions and make some tasks for self-management.

More on this on *CW+AsiaHub*

Dennis Engbarth (Taipei City)

Related Articles

- Vietnam updates draft existing chemicals inventory
- Vietnam publishes new chemical decree
- Vietnam to introduce national database by 2019 at earliest

Spanish initiative targets child poisoning from 'everyday' products

23 November 2017 / Accidents, emergency response & poison centres, Cleaning products, Labelling, Spain

The Spanish consumers federation, CECU, has launched a new initiative to raise awareness of chemicals contained in glues and paints, used daily by children. It will also target household products, such as detergents, to prevent incidents of poisoning.

The project – Ojo a la Etiqueta (Watch the label) – will promote knowledge about the labelling and safe use of stationery items, including markers and correctors, as well as cleaning products and insecticides used at home.

"Every year thousands of accidents related to poisoning occur, of which more than 93% happen in the home and more than 45% affect children under ten years," CECU said in a statement.

The project, to be carried out in collaboration with the Spanish chemicals industry association (Feique), will be presented in Madrid today. Mercedes Vinas, Echa's head of unit for dossier submission, will be at the launch.

The CECU says it has prepared ten training sheets for parents, tutors and teachers with advice on what to do if a child swallows paint, glue or medication, and how to act in case of poisoning. The material will also be available on the CECU website.

It has also created a mobile app with:

- access to the sheets;
- rapid advice in case of poisoning; and
- a direct dial button to the Toxicological Information Service.

The initiative, subsidised by the Spanish agency for consumer affairs, food safety and nutrition (AECOSAN), will be disseminated in social networks and has the hashtag #OjoALaEtiqueta.

Earlier this year, soap and detergents trade body Aise said some of its members plan to undertake voluntary measures, to help reduce child exposure to liquid laundry detergent capsules (LLDCs). These will include superior child-impeding closures and an advertising code of conduct.

It followed European Commission's LiquiCaps study, which highlighted an increase in the numbers of accidental exposure or poisoning in children under five, when compared with traditional detergents.

Related Articles

- Aise proposes measures to reduce detergents poisoning in children

Further Information:

- Press release (Spanish)

Echa: non-animal tests for complex endpoints remain distant

Regulatory applicability 'not foreseen' in near or medium term

23 November 2017 / Biocidal products Regulation, Classification, Classification, labelling and packaging Regulation, Europe, GHS, REACH, Test methods

Non-animal approaches for the prediction of higher-tier hazard endpoints that would be applicable under EU chemical legislation are "not foreseen" in the near or medium term, according to analysis by Echa.

Non-animal approaches in general are the subject of "very active ongoing research", the agency said in a report on the current status of regulatory applicability of such approaches under the REACH, CLP and biocidal products Regulations. Furthermore, those for the prediction of certain lower-tier endpoints, such as skin irritation, corrosion and sensitisation, have become standards, as defined by the legislation.

But non-animal approaches for the prediction of more complex endpoints, such as repeated dose or reproductive toxicity, remain far off, the report said.

Challenges

The report outlines several challenges to the development of such approaches and their uptake in regulatory contexts.

First, they do not always provide the same levels of information as their animal equivalents in terms of the dose- or concentration-response relationship and adverse effects, it says. Some still under development could provide higher levels of information than current ones. These include approaches based on *in vitro* microsystems and high-throughput or high-content approaches. But these will still require standardisation and validation before they can be used in regulatory contexts.

Second, standardisation and validation is complicated by the plurality of approaches required, compared with animal equivalents. Regulators must work out how data generated by non-animal approaches that do not have a direct relationship with an endpoints specified in CLP, can be used for classification and for the derivation of safe use levels.

The agency suggests that an inventory of non-animal approaches that shows stage of development and regulatory applicability would help to identify gaps and determine future steps to enhance use.

The report, requested by Echa's management board, is the first of its kind. In previous reports, requested by the European Commission and published in 2011, 2014 and 2017, Echa provided data on companies' use of non-animal approaches under REACH.

In contrast, for each relevant information requirement, the new report provides:

- the potential non-animal approaches;
- the challenges to achieving their use in regulatory contexts; and
- future perspectives, including of those approaches that could be close to regulatory applicability.

In a foreword, outgoing Echa executive director Geert Dancet says he hopes the report will act as a guide for the scientific community.

Animal rights NGO Humane Society International (HSI) questioned "the continued emphasis on animal methods as the basis for comparison of the viability of new methods". Such emphasis presumes that toxicology studies on animals are the only valid approach, it said.

"These words must now be backed-up by more positive practical action and financial support for the promotion of non-animal approaches."

Furthermore, future reviews should be led by "mandated bodies", such as the European Commission Reference Laboratory for Alternatives (EURL-Ecvam), HSI said.

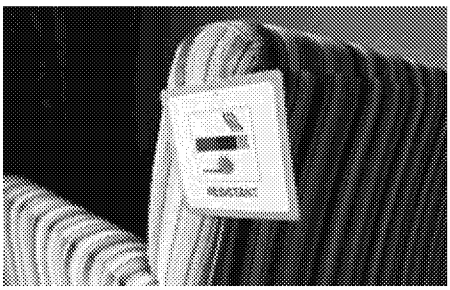
Further Information:

- Report

Furniture trade body welcomes EU warning on flame retardants

Member states urged to evaluate testing methods for upholstered items

23 November 2017 / Built environment, Europe, Substances of concern



The European Furniture Industries Confederation (Efic) has welcomed a warning, included in the revised EU Green Public Procurement criteria, on the negative effects of flame retardant use.

GPP criteria for furniture are voluntary guidelines, which aim to help public authorities purchase products and services with reduced environmental impacts.

In the staff working document on the EU GPP, the European Commission notes that the open flame test for upholstered furniture (EN 1021-2) requires a lower level of flammability than the European 'smoulder ignition test' (EN 1021-1).

It says the open flame test can lead to use of flame retardant chemicals which "may have negative effects for the environment, health, durability and quality of products, and may lead to cost increases".

The guidelines urge public authorities to "therefore consider, according to the intended use and location of the furniture items, what levels of flammability it needs to require."

'A first step'

Efic general secretary, Roberta Dessi, told Chemical Watch that the association was glad the Commission had adopted this recommendation.

She said: "It is a first step. We believe that this can help raise awareness among member states about the consequences of choosing certain flammability tests for furniture."

But she added that the "sustainability part" of public tenders is often accompanied by demands for very stringent flammability standards. This leads to widespread use of flame retardants "in contradiction with the aim of having truly green procurements".

She urged member states to "use this feedback to re-evaluate the need for such stringent standards for furniture in their national requirements, in the light of the overwhelming scientific evidence on risks connected to flame retardant use."

The UK and Ireland are the only EU countries to have national regulations requiring an open flame test for domestic furniture, which effectively necessitates the use of flame retardants. Last year, Efic lodged a complaint with the Commission on the basis that these standards pose a barrier to trade in the single market.

For furniture for the public market there are different national regulations in force, some of which also impose open flame tests.

Furniture design

The GPP criteria technical report acknowledges that the need for flame retardants can potentially be avoided by "careful choice of materials and product design". But it says that this type of upholstered furniture "can be considered to only represent a niche market at this stage and, unlike California, current fire safety standards in Europe for public furniture are currently not well set up to embrace this approach."

California removed its open flame test in 2013. Prior to that, California's Technical Bulletin (TB) 117 had served as the de facto national standard, which effectively required the use of flame retardants.

The report adds that the lack of a harmonised approach to fire safety standards, at the European level, means that "any potential restrictions on flame retardants, recommended in EU GPP criteria, may conflict with specific member state legislation."

Ms Dessi responded: "Our campaign is aimed at having a more proactive approach from European institutions, in making the case for flame retardant free furniture possible."

She also noted: "In addition to the environmental and health impact, there is a growing concern that flame retardants may increase fire toxicity. This would also seriously question any concrete fire safety benefit from their use."

Efic is a member of the Alliance for Flame Retardant Free Furniture in Europe, a coalition of stakeholders including industry associations and environmental NGOs.

Last year, the coalition published a paper, *The Case for Flame Retardant free Furniture,* calling for the EU to harmonise fire safety regulations so that the chemicals were not required for them to be met.

Efic have argued that the use of flame retardants and other chemicals may prevent the furniture sector from fully entering the circular economy.

Earlier this year, San Francisco banned the sale of upholstered furniture and children's products, "made with or containing an added flame retardant chemical". More than a dozen US states have banned some categories of the chemicals.

Tammy Lovell

Business Reporter

Related Articles

- EU Commission publishes green public procurement criteria for furniture
- Industry challenges UK and Irish furniture standards
- Industry challenges UK and Irish furniture standards
- Furniture trade body calls for clarity on recyclable chemicals
- San Francisco bans sale of furniture treated with flame retardants

Further Information:

- GPP working document
- EU GPP technical report
- The Case for Flame Retardant Free Furniture report

ToxCast and Tox21 high-throughput data identify potential EDCs

Fifra SAP set to discuss androgen receptor model

23 November 2017 / Alternative approaches to testing, EDCs, United States

ToxCast and Tox21 high-throughput screening data provide a "rapid and effective resource" for identifying substances with the potential to activate human oestrogen (estrogen) receptors (ERs), according to a top US Environmental Protection Agency (EPA) official.

Stan Barone, acting director of the EPA's Office of Chemical Safety and Pollution Prevention, was describing progress in using ER high-throughput assays for tier 1 of the Endocrine Disruptor Screening Program (EDSP) at a workshop on toxicity testing and decision making.

The EDSP uses an oestrogen receptor model that integrates data from 18 high-throughput assays. The agency has recently been looking into whether it actually needs all of the tests to get the same predictive validity from the model, and has a publication in press. "The short answer is we don't need 18 assays," said Dr Barone.

The EDSP is making good progress on an androgen receptor model, which integrates 11 *in vitro assays*, he added.

The Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (Fifra SAP) is set to discuss the tests between 28 and 29 November.

Limitations

Like most alternative approaches, the high-throughput assays have limitations, Dr Barone explained. These include metabolism and solubility issues. False negatives can result from low solubility, which limits test chemical concentrations. Furthermore, reactive compounds, metals and particulates tend not to work well in the low volume, high-throughput assays, he added. The EPA is conducting research to address these issues.

The agency is also looking into "critical performance criteria" to include in a performance-based guideline to help stakeholders understand data and documentation requirements.

One of the lessons learned is that annotating assays is "critically important for acceptance", said Dr Barone.

Understanding pathways to a paradigm shift in toxicity testing and decision making was held by the National Academies of Sciences, Engineering and Medicine in Washington DC between 20 and 21 November.

Related Articles

- NICEATM and EPA publish androgen receptor model

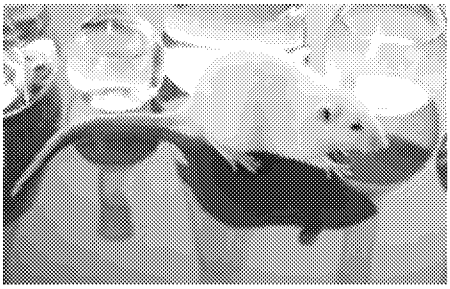
Further Information:

- Understanding pathways to a paradigm shift in toxicity testing and decision making
- Fifra SAP white paper

US NAS workshop raises issue of animal tests as 'gold standard'

Greatest progress where human data available

23 November 2017 / Test methods, United States



The issue of whether animal test methods should be used as as a "gold standard" against which to judge the alternatives was raised by multiple attendees at a recent US workshop on toxicity testing and decision making.

"It is one of the big challenges that we face," said Anna Lowit, co-chair of the Interagency Coordinating Committee on the Validation of Alternative Methods (Iccvam) and senior science adviser at the US EPA's Office of Pesticide Programs.

"One of the things that we are finding is that we are having the most success in areas where human data exists to make those comparisons," she added. As an example, she pointed to recent research suggesting that OECD test guidelines for skin sensitisation may give better predictions of human toxicity than the local lymph node assay (LLNA) in rodents.

Maurice Whelan, head of the EU Reference Laboratory for Alternatives to Animal Testing (EURL Ecvam), described the relevance and variability of animal test results as the "elephant in the room". In the case of alternative skin sensitisation test methods, discussing it with regulatory committees resulted in an important step forwards. "What's the variability of the LLNA data? ... From the human data that we have, we know it's not perfect."

Rodent retreat

Meanwhile, Dr Lowit spoke of progress in moving away from rodent tests for skin irritants, and effects in the nasal cavity and lung tissue.

"Industry partners are working towards actually eliminating the 28-day and 90-day rate inhalation study, just because it's not really relevant to humans," she said. "We can do better with animal 3D tissues combined with sophisticated pharmacokinetic modelling and just avoid the animal completely."

She predicted that: "When we start to tackle complicated things, like cancer and developmental reprotoxicity, we will have enough experience under our belt, in a way that we won't have to hold up the rat and the mouse models as a gold standard."

The importance of uncertainty

Finally, workshop participants agreed on the need to understand the uncertainties associated with alternative test methods.

The skin sensitisation case "highlights the importance of something that we have neglected for many years: appreciating that, in fact, understanding uncertainty, describing it, talking about it, is extremely important for moving towards people using new approaches," said Professor Whelan.

"The good news is that we won't have to start from scratch. There is an awful lot of rigorous scientific-based work being done on how to go about describing uncertainties."

Understanding pathways to a paradigm shift in toxicity testing and decision making was organised by the US National Academies of Sciences, Engineering and Medicine and held in Washington, DC on 20-21 November.

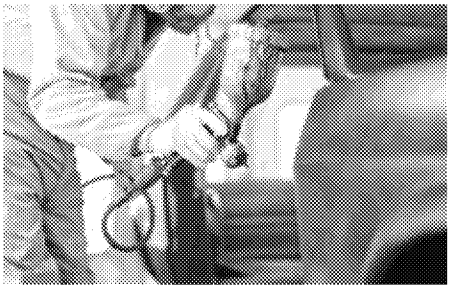
Further Information:

- Understanding pathways to a paradigm shift in toxicity testing and decision making

REACH exposure scenario group looks for improvements

New batch of updated use maps to be published soon

24 November 2017 / Europe, Exposure scenarios



Stakeholders of the REACH Exchange Network on Exposure Scenarios (Enes) have been discussing a draft programme that will take its work through until 2020, at its eleventh meeting in Helsinki this week.

The network aims to improve the content and use of exposure scenarios generated under REACH. They are a key element of safe use communication through the supply chain through the extended safety data sheet.

Erwin Annys, REACH director at Cefic, told stakeholders – including representatives from Echa, up and downstream industry and member state authorities – the programme aims to tackle six issues:

- promotion of the Enes tools to various stakeholders;
- support for downstream sectors developing use maps;
- support for registrants in applying new use information in their chemical safety reports, and communicating safe use information through the supply chain. Proposed activities include adapting the software tool Chesar and building a common practical framework for various estimation tools relating to worker exposure;
- improving tools for formulators;
- further market research especially to help downstream users; and
- improving the interface between REACH and occupational safety and health controls.

The programme will be finalised early next year, and presented to the Competent Authorities for REACH and CLP (Caracal) in March.

Updated sector use maps

Meanwhile, a raft of updated REACH sector specific use maps are expected to be published shortly on Echa's website. The agency's Laure-Anne Carton de Tournai, said that 13 sectors are currently active in the programme.

So far six groups have published the standardised information. This aims to provide realistic descriptions of chemical uses and, depending on their relevance, inputs for worker, consumer and environmental exposure, in their industries.

Another five sector groups – paints and coatings, plastics additives, petroleum products, solvents and fertilisers – will be published soon.

Ms Carton de Tournai also gave figures for how many files had been downloaded from the Echa use map library.

The detergents sector, represented by Aise, which had its documents published in October 2016, has had nearly 5,800 downloaded; and the adhesives and sealants industry (Feica) has had more than 3,500 documents downloaded since November 2016.

Ambition

Echa is unclear on exact use of the documents. Originally the ambition was for the updated use maps to be implemented in 2018 dossiers. However, this has not occurred, and the hope now is they will be used to update dossiers after the deadline.

Speaking for the European Solvents Industry Group (Esig), Cornelia Tietz said assessment of generic exposure scenarios developed for solvent uses for the 2010 REACH deadline showed good alignment with the new batch of use maps and specific worker exposure determinants.

Dook Noij of Dow outlined a pilot project trying to quantify the benefits of the harmonised communication package ESCom XML, and standard ESCom phrases. The project indicated that manual exposure scenario data input takes between 2-4 hours, compared to five minutes to quality check electronic submissions – if all phrases exist in ESCom. If there are phrases missing, the estimated time is up to an hour.

Mr Noij noted that the initial effort needed to implement ESCom XML can be significant, but he said the benefits included improved use of resources and expertise, and faster processing.

Emma Chynoweth

Chief Customer Officer

Further Information:

- Enes 11
- Use map library

OTHER ARTICLES

Jennifer Jelinek: Finalize EPA toxic chemical rules

Madison.com

Dear Editor: Thanks to the 2016 update of U.S. chemical policy, the EPA now has the authority to protect us from toxic chemicals. EPA proposed rules ...

Vt. toxics law provides data, but not clarity, about kids' toys

BurlingtonFreePress.com

Companies reporting any of the 66 chemicals to Vermont included ... has worked for years to help Vermonters know more about **toxic chemicals**.

Toxic chemical found in children's products

KIMT 3

Toxic chemical found in children's products ... The toxin is a cheap chemical some companies use instead of lead. It's been linked to bone damage, ...

Toxic chemical found in children's products

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Toxic chemical found in children's products ... The toxin is a cheap chemical some companies use instead of lead. It's been linked to bone damage, ...

Group finds many consumer products still contain **toxic chemicals**

ConsumerAffairs

Photo (c) gilaxia - Getty Images In a report on **toxic chemicals** contained in consumer products, a consumer group finds two thirds of retail companies it ...

Advocacy group Safer **Chemicals**, Healthy Families rates **toxic** retailers

CosmeticsDesign.com USA

A Report Card on Retailer Actions to Eliminate **Toxic Chemicals** purports to rate stores based on their efforts to limit or regulate "**toxic chemicals** in ...

Letter: A **toxic** EPA pick

Concord Monitor

But he is not someone you can trust to protect your children from **toxic chemicals**. In fact, it is his extensive background as a paid researcher for the ...

Annual 'Trouble in Toyland' report highlights dangerous small parts and confusing labels

KOMO News

... from toys and other children's products made with harmful **toxic chemicals**. ... But there are numberous chemicals that must still be addressed.

California should expand on San Francisco's flame retardants ban

San Francisco Examiner

A lack of statewide action to eliminate **toxic**, flame retardants continues to jeopardize their health, along with the health of all Californians. “We're long overdue for bold statewide policy prohibiting the unnecessary use of flame-retardant **chemicals**,” Debbie Raphael, director of the San Francisco ...

Touching receipts can lead to lengthy pollutant exposures

Science News for Students

Over the next several days, the researchers measured how much of the tagged BPA came out in the mens' urine. This showed how quickly the body was processing and removing the chemical. (Waste products, including BPA and other **toxic chemicals**, are filtered out of the bloodstream by the kidneys.

Explainer: Store receipts and BPA

Science News for Students

By the early 2000s, Warner was teaching **green chemistry** at the University of Massachusetts in Boston and Lowell. “I'd send my students out to local stores to get their cash register receipts.” Back in the lab, they'd dissolve the paper. Then they'd run it through a mass spectrometer. This instrument could ...